

## REMARKS/ARGUMENTS

### STATUS OF THE CLAIMS

Claims 1, 5, 10, 18 and 21-23 are pending with entry of this amendment, claims 2-4, 6-9, 11-17, 19, 20 and 24-54 having been cancelled previously.

### AMENDMENTS TO THE CLAIMS

Claim 1 is amended herein. This amendment introduces no new matter and support is replete throughout the specification. The amendment is made without prejudice and is not to be construed as abandonment of the previously claimed subject matter or agreement with any objection or rejection of record.

Support for the amendment to claim 1 specifying that the plant is generated from the transformed cells without going through an undifferentiated intermediate is replete throughout the specification. For example, see the specification at paragraphs [0045], [0047], [0049] and elsewhere.

Applicant submits that no new matter has been added to the application by way of the above Amendment. Accordingly, entry of the Amendment is respectfully requested. Applicant traverses all rejections and objections, to the extent that they are applied to the amended claims.

### THE CLAIMS ARE NOT OBVIOUS

Claims 1, 5, 10, 18, 21 and 22 were rejected under 35 U.S.C. §103(a) as allegedly obvious over Sripaoraya et al. (*Annals of Botany* (October 2001) 88: pp. 597-603) (“Sripaoraya”) in view of U.S. Patent No. 5,952,543 (“the ‘543 patent”). Especially to the extent that the rejections are applied to the amended claims, Applicant respectfully traverses for the reasons set forth below.

According to the post-KSR Patent Office promulgated examination guidelines on determination of obviousness, when office personnel reject claims by attempting to combine prior art elements according to allegedly known methods to yield predictable results, the Office must resolve the Graham factual inquiries and articulate:

(1) “a finding that the prior art included each element claimed, although not necessarily in a single prior art reference, with the only difference between the claimed invention and the prior art being the lack of actual combination of the elements in a single prior art reference;”

(2) “a finding that one of ordinary skill in the art could have combined the elements as claimed by known methods, and that in combination, each element merely would have performed the same function as it did separately; and”

(3) “a finding that one of ordinary skill in the art would have recognized that the results of the combination were predictable.” (Federal Register / Vol. 72, No. 195 / Wednesday, October 10, 2007 / Notices at 57529, *citing KSR International Co. v. Teleflex Inc.*, 82 U.S.P.Q. 2d 1385, 1395 (U.S. 2007)).

Thus, the rationale to support a conclusion that a claim would have been obvious is that “all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions,” and that “the combination would have yielded nothing more than predictable results to one of ordinary skill in the art at the time of the invention.” *Id.*

**No reasonable prediction existed at the time of filing that Agrobacterium-mediated gene transfer could successfully transform organogenic leaf base tissue**

The stated rationale in the Action for concluding that the claimed invention is obvious over Sripaoraya, in view of the ‘543 patent, is as follows:

It would have been obvious at the time of filing to substitute the transformation of Pineapple using the Agrobacterium methodology taught by Firoozabady for that of Sripaoraya. One of ordinary skill would have [been] motivated by the success of Firoozabady in transforming Pineapple using Agrobacterium and had a reasonable expectation of success given the success of Firoozabady and Sripaoraya in transforming Pineapple . . . . See Action at p. 3.

Applicant respectfully disagrees, at least because Agrobacterium-mediated transformation of leaf base tissue was not taught or suggested in the art, and the success of this approach for transforming leaf base tissue (demonstrated by Applicant at, e.g., Examples 1 and 2 of the specification) would not have been predictable by one of skill in the art at the time the application was filed. The ‘543 patent relates to Agrobacterium-mediated

transformation of *embryogenic callus cells*, which constitutes an entirely different target for transformation as compared to the organogenic leaf base tissue of the present invention. It was well understood in the art at the time of the invention that Agrobacterium-mediated gene delivery is highly sensitive to the type of cells/tissue to be transformed. In fact, a plain reading of Sripaoraya would steer one of skill away from using Agrobacterium to transform organogenic leaf base tissue. For example, Sripaoraya acknowledges the prior use of Agrobacterium-mediated gene transfer using embryogenic callus as target tissue. See Sripaoraya at p. 597 (the paragraph bridging the left and right columns). However, Sripaoraya provides no suggestion or motivation to use Agrobacterium-mediated gene delivery for transformation of leaf bases. In fact, Sripaoraya makes a point to specifically tout “microprojectile-mediated gene delivery into leaf bases of micropropagated shoots [as] an effective method for the production of transgenic pineapple” (see Sripaoraya at p. 602), while making no mention whatsoever of Agrobacterium-mediated gene delivery as a viable transformation alternative.

Given the general unpredictability of Agrobacterium-mediated transformation, the absence of any evidence in the prior art of the feasibility of this approach as applied to leaf bases, and Sripaoraya’s express endorsement of microprojectile bombardment as the method of choice for transforming leaf base tissue, one of skill would not have been able to predict whether Applicant’s method for organogenic transformation of leaf bases, and direct regeneration of pineapple plants therefrom, would be successful. At least for these reasons, the claims are not obvious and the rejections should be withdrawn.

**The cited references fail to teach each limitation of the claimed invention**

Applicant also traverses the rejections for alleged obviousness on the ground that the cited references fail to teach each element of the claimed invention, especially as amended herein. For example, whether or not Sripaoraya characterizes their method as not involving a callus intermediate during regeneration, it is readily apparent to one of skill in the art that the method disclosed therein entails the generation of an undifferentiated tissue intermediate subsequent to transformation. The reasons for this are set forth in the declaration submitted concurrently herewith. In brief, it is apparent from, e.g., the color photo of Figure 1B of Sripaoraya, that the transformed leaf base tissue proceeds through an

unorganized/undifferentiated callus intermediate prior to shoot production. This result is expected, as one of skill in the art of pineapple tissue culture would recognize that culturing leaf bases in MSDB medium containing 1 mg/L each of 2,4-D and BAP (see Sripaoraya at p. 597, left column) results in unorganized/undifferentiated tissue during the regeneration process.

To more clearly distinguish the method described in Sripaoraya from that of the present invention, claim 1 is amended herein to specify that the plant is generated from transformed organogenic cells without going through an “undifferentiated” intermediate. At least because neither Sripaoraya nor the ‘543 patent teach this limitation of claim 1, the claims are not obvious and the rejections should be withdrawn.

#### DOUBLE PATENTING

Claims 1, 5, 10, 18 and 21-23 are rejected on the ground of nonstatutory obviousness-type double patenting as allegedly unpatentable over claims 1-26 of U.S. Patent No. 7,663,021. Applicant respectfully traverses. However, when the claims are otherwise in condition for allowance, Applicant will determine whether the filing of a terminal disclaimer (e.g., to facilitate prosecution) is appropriate to address any maintained rejections for alleged double patenting.

## CONCLUSION

In view of the foregoing, Applicant believes all claims now pending in this application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the claims are deemed not to be in condition for allowance after consideration of this response, a telephone interview with the Examiner is hereby requested. Please telephone the undersigned at (510) 337-7871 to schedule an interview.

The Commissioner is hereby authorized to charge any additional fees associated with this paper or during the pendency of this application, or credit any overpayment, to Deposit Account No. 50-0893.

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Respectfully submitted,



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Attachments:

- 1) A petition to extend the period of response for 1 month;
- 2) a transmittal sheet;
- 3) a fee transmittal sheet;
- 4) an expert declaration; and,
- 5) a receipt indication postcard.